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PATENT APPLICATION

REMARKS/ARGUMENTS

This is in full and timely response to the final Office Action dated July 5, 2005 (Paper No. 06232005). Reconsideration of the Examiner's rejections in the final Office Action are respectfully requested in view of the following remarks.

Claims 2, 3, 5, 6, 24, 28, 29, 31, 32, 36, 37, 50 and 51 remain pending in this application. No amendments after final are proposed at this time.

Finality of Office Action Improper

The finality of the last Office Action is believed to be improper. The Applicant's prior amendment did NOT necessitate the new grounds of rejection, which were presented for the first time in the final Office Action. The scope of independent claims 28 and 36 was not changed at all by the Applicant's prior amendment. Instead, these claims were merely rewritten into independent form and have the same scope as originally presented. If, after considering the Applicant's prior remarks, the Examiner determined that the new grounds of rejection were appropriate (for the same claims as initially presented), such new grounds of rejection should have been made in a second NONFINAL Office Action. See Manual of Patent Examining Procedure ("MPEP") Section 706.07(a). Accordingly, the Examiner is respectfully requested to withdraw the finality of the last Office Action.

Rejection of Claims 2, 3, 5, 6, 24, 28 and 29 Based on Sarge et al. In View of Klint and Pursley

Claims 2, 3, 5, 6, 24, 28 and 29 stand rejected under 35 U.S.C. 103(a) as allegedly being

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unpatentable over Sarge et al. (U.S. Patent Publication No. 2001/0041881) in view of Klint (U.S. Patent Publication No. 2001/0044633), and further in view of Pursley (U.S. Patent No. 6,030,371). This rejection is respectfully traversed for the following reasons.

Sarge et al. discloses a catheter having continuous lattice and coil reinforcement for performing medical procedures. The catheter includes an inner tubular member with a lumen and a support member overlaying the inner tubular member. The support member includes a multilayered portion with each layer comprising a plurality of turns formed by a single filament 300. In the described embodiment, the winding of the filament 300 proceeds from a distal end of the catheter towards the proximal end. At a desired point near the proximal end, the winding direction is reversed so that the filament 300 moves back toward the distal end with turns 306 that overlay turns 304 of the first layer 82. The winding of filament 300 again changes directions and proceeds back toward the proximal end with a third layer 86 of turns 308 that overlay the turns 306 of the second layer 84.

Sarge et al. does not teach or suggest of the step of winding a group of filaments simultaneously, nor the step of providing a guide assembly for a group of filaments, as recited in claim 28.

The Examiner relies upon Klint for a teaching of winding a group of filaments simultaneously, and particularly refers to paragraph 0015 of Klint. The Examiner further relies upon Pursley '371 for a teaching of a guide assembly having a filament engaging surface arranged as recited in claim 28. However, none of these three references teach a guide assembly for winding a group of filaments simultaneously as claimed.

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Klint discloses a medical device, such as a catheter, having a body portion 3 with a central longitudinally extending lumen 6 and a multiple filament helically wound row A of wires 5. The wires 5 are placed in a row next or closely adjacent to each other, and the group of wires is wound according to a desired pitch angle onto the body portion. Klint discloses a method of winding the wires 5 using a mandrel 7, as shown in Fig. 7 (see, e.g., page 3, paragraph 0049). After winding the wires 5 onto the mandrel 7, the coiled wires are heated to remove residual stresses from the wires. After the heat treatment, the mandrel 7 is then removed from the wires 5, leaving the wires 5 to maintain their positions. Although Klint does not describe or show a guide assembly for guiding the wires 5 to the mandrel 7 during the winding process, it can be seen in Fig. 7 of Klint that the wires 5 are fed during the winding process to the outer surface of the mandrel 7 in a plane which is generally parallel to the longitudinal axis of the mandrel 7. Even if some sort of guide assembly is inherent in the teachings of Klint, such guide assembly is clearly not one with a filament engaging surface that "lies in a plane which is generally perpendicular to a longitudinal axis of the core member."

Pursley '371 discloses a catheter and a method for nonextrusion manufacturing of catheters. Among other things, Pursley '371 discloses methods and apparatus for winding filament material onto a catheter liner before a polymer material is applied over the catheter liner. Pursley '371 does not teach winding a group of filaments simultaneously onto the catheter liner, and certainly does not teach a guide assembly having a filament engaging surface arranged in the manner recited in claim 28. Indeed, Pursley '371 lacks any teaching of a structure corresponding to the Applicant's claimed guide assembly having a filament engaging surface.

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In explaining this rejection, the Examiner states on page 3 of the final Office Action as follows:

Pursley teaches providing a guide assembly having a filament engaging surface, and arranging said guide assembly such that the filament engaging surface lies in a plane which is generally perpendicular to a longitudinal axis of the core member (Figure 1b). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use the guide assembly taught by Pursley in the process taught by Sarge et al. The motivation to do so would have been to achieve a winding angle range that is far superior to the range achieved by other braiding/wrapping operations (Pursley, column 5, lines 45-51).

Fig. 1b of Pursley '371 shows only a core mandrel 10 and a catheter liner 12. No details of a structure for applying reinforcement filament are provided in Fig. 1b. Thus, the Examiner has failed to identify any structure in Pursley '371 that corresponds to the claimed guide assembly having a filament engaging surface.

Moreover, the filament winding head 16, reinforcement filament 20, and partially wrapped catheter liner 12 shown in Fig. 1c of Pursley '371, also fail to provide a guide assembly having a filament engaging surface as claimed. The filament winding head 16 of Pursley '371 is shown in more detail in Fig. 2. In Fig. 2, it can be seen that: (1) only one filament 20 is being applied at a time; (2) the filament 20 passes directly from a spool 21 to the catheter liner 12 without engaging a guide assembly; and (3) there is no structure in Pursley '371 that can be construed as the claimed guide assembly having a filament engaging surface arranged in the manner recited in the Applicant's claim 28.

The Examiner contends that it would have been obvious at the time of the Applicant's invention to wind a group of filaments simultaneously in the process taught by Sarge et al., in

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view of the multiple filament teachings of Klint. However, neither of the applied references teaches the claimed process of reversing a direction of winding when applying a group of filament windings simultaneously. Klint only teaches a single direction of winding for a group of filaments, while the direction reversal taught by Sarge et al. is only in connection with a single filament strand.

The Examiner further contends that the step of providing a guide assembly, as recited in claim 28, is taught by Pursley '371. However, as explained above, the Examiner does not identify any specific teachings or elements of Pursley '371 that can be construed as the claimed guide assembly having a filament engaging surface that lies in a plane which is generally perpendicular to a longitudinal axis of the core member. Further, the Examiner does not explain any teaching, suggestion or motivation found in any of the applied references for modifying Sarge et al. to incorporate the guide assembly allegedly taught by Pursley '371, and particularly not to use such a guide assembly for guiding a group of filaments being wound simultaneously.

As explained above, Klint teaches away from a guide assembly having a filament engaging surface arranged to lie in a plane which is generally perpendicular to a longitudinal axis of the mandrel. Specifically, Klint teaches in Fig. 7 a group of filaments that are oriented in a plane which is parallel to the longitudinal axis of the mandrel, instead of perpendicular to the mandrel axis.

In contrast, the Applicant's invention uses a guide assembly having a filament engaging surface that lies in a plane which is generally perpendicular to a longitudinal axis of the core member. The group of filaments leave the filament engaging surface of the guide assembly in a

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plane which is perpendicular to the core member. As the group of filaments make contact with the core member, the filaments naturally re-orient themselves into a parallel plane with the axis of the core member as they are wrapped onto the core member. This provides a relatively simple, yet highly effective method of forming a "band" of filaments on the core member. This claimed feature of the Applicant's invention allows the filaments within a group of filaments to be positioned side-by-side and packed tightly against one another as the group of filaments are wound onto the core member. As a result, a high number of filaments can be laid in a single band.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw his rejection of claim 28 under 35 U.S.C. 103(a) based on Sarge et al. in view of Klint and further in view of Pursley '371. Claims 2, 3, 5, 6, 24 and 29 all depend, either directly or indirectly, upon claim 28, and are believed to be patentable for at least the same reasons explained above regarding claim 28.

With further regard to claim 2, it is respectfully submitted that Sarge et al. do not teach anchoring a filament at or near a proximal end of the core member before winding the filament onto the core member, as stated by the Examiner. Instead, Sarge et al. specifically teach that the filament 300 is anchored at the distal end of the core member before winding the filament. Specifically, Sarge et al. state in the second sentence of paragraph 0063 that the method begins with "temporarily or permanently securing distal portion 192 of filament 300 to inner tubular member 30 proximate its distal end." Accordingly, claim 2 is believed to be allowable for this additional reason.

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Rejection of Claim 29 Based on Sarge et al. In View of Klint, Pursley and McMickle et al.

Claim 29 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sarge et al. in view of Klint, Pursley '371 and McMickle et al. (U.S. Patent No. 4,484,586). The Examiner contends that the combined teachings of Sarge et al. in view of Klint and Pursley '371 provide the invention of claim 29, except for the step of varying a rotation speed of the core member or a translation speed of the filament source along the core member.

This rejection of claim 29 is respectfully traversed for at least the same reasons explained above regarding the allowability of the independent base claim 28. Accordingly, reconsideration and withdrawal of the rejection of claim 29 are respectfully requested.

Rejection of Claims 32, 36 and 37 Based on Klint in view of Sarge et al. and Pursley

Claims 32, 36 and 37 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Klint in view of Sarge et al. and Pursley '371. The teachings of Klint and Sarge et al. are explained above. The Examiner contends that Klint discloses the claimed invention, except for the claimed step of rotating the core member relative to a source of the filaments and passing the source of filaments in a first direction of axial movement relative to the core member, and the claimed step of providing a guide assembly having a filament engaging surface arranged as claimed. This rejection is respectfully traversed for the following reasons.

As explained above in response to the Examiner's rejection of claim 28, Pursley '371 does not teach or suggest a guide assembly having a filament engaging surface, and particularly not one having a filament engaging surface arranged to lie in a plane which is generally

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perpendicular to a longitudinal axis of the mandrel or one used in connection with multiple filament strands. The filament 20 in Pursley '371 is disclosed in Fig. 2 as passing directly from a filament spool 21 to the surface of the catheter liner 12 without touching anything that could be construed as a filament engaging surface. Moreover, any filament engaging surface used in connection with a single filament strand winding such as taught by Pursley '371, instead of a group filament winding, would have little, if any, relevance to the Applicant's claimed invention. It is also noted that Klint teaches away from a guide assembly arranged in the manner presently claimed by illustrating in Fig. 7 a group of filaments that are oriented in a plane which is parallel to the longitudinal axis of the mandrel, instead of perpendicular to the mandrel axis.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw his rejection of independent claim 36 under 35 U.S.C. 103(a) based on Klint in view of Sarge et al. and Pursley '371. Claims 32 and 37 depend, either directly or indirectly, upon claim 36, and are believed to be patentable for at least the same reasons explained above regarding claim 36.

With further regard to claim 32, it is respectfully submitted that Klint does not teach the claimed step of winding a group of filaments with a variable pitch such that a filament group spacing at a distal end of the core member is narrower than a filament group spacing at a proximal end of the core member. Instead, paragraph 0050 of Klint teaches only that the pitch angle of the wires can be varied for different segments of the catheter, not the spacing between the groups of wires. Klint teaches in paragraph 0049 that an interstice B is preferably provided between the wire turns, but does not teach the claimed step of making the interstice B narrower at a distal end of the catheter than at the proximal end. Accordingly, claim 32 is believed to be

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allowable for this additional reason.

With further regard to claim 37, it is respectfully submitted that neither of the applied references of Sarge et al. and Klint teaches the claimed process of reversing a direction of winding when applying a group of filament windings simultaneously. Klint only teaches a single direction of winding for the group of filaments, while the direction reversal taught by Sarge et al. is only in connection with a single filament strand.

Moreover, the Examiner's stated motivation for combining the references to reject claim 37 is stated on page 6 of the Office Action as follows:

"to form two layers of filaments to build a catheter having two or more discrete tubular members having different performance characteristics (Sarge et al., paragraph 0011)."

This stated motivation is not understood and does not appear to have any relevance to the proposed combination of Klint and Sarge et al. The discrete tubular members mentioned in paragraph 0011 of Sarge et al. are not part of Sarge et al.'s invention; they are described as one of the prior art devices that Sarge et al.'s invention was trying to avoid. If anything, such discrete tubular members are a teaching away from the claimed invention.

Rejection of Claim 31 Based on Klint In View of Sarge et al., Pursley and McMickle et al.

Claim 31 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Klint in view of Sarge et al., Pursley '371 and McMickle et al. The Examiner contends that the combined teachings of Klint in view of Sarge et al. and Pursley '371 provide the invention of claim 31, except for the step of varying a rotation speed of the core member or a translation

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speed of the filament source along the core member.

This rejection of claim 31 is respectfully traversed for at least the same reasons explained above regarding the allowability of the independent base claim 36. Accordingly, reconsideration and withdrawal of the rejection of claim 36 are respectfully requested.

Rejection of Claim 50 Based on Sarge et al. In View of Klint

Claim 50 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sarge et al. in view of Klint. The Examiner contends that Sarge et al. disclosed the claimed invention, except for the step of winding a group of filaments simultaneously. The Examiner relies upon Klint for this teaching. This rejection is respectfully traversed for the following reasons.

Claim 50 recites, among other things, a method of making a catheter in which a group of filaments are anchored (at least temporarily) to a proximal end of the catheter and then wound onto the catheter continuously from the proximal end to the distal end, and then back to the proximal end. As explained above in connection with the rejection of claim 2, Sarge et al. do not teach anchoring a filament at or near a proximal end of the core member before winding the filament onto the core member, as stated by the Examiner. Instead, Sarge et al. teach that the filament 300 is anchored at the distal end of the core member before winding the filament. Specifically, Sarge et al. state in the second sentence of paragraph 0063 that the method begins with "temporarily or permanently securing distal portion 192 of filament 300 to inner tubular member 30 proximate its distal end."

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Accordingly, the Examiner is respectfully requested to reconsider and withdraw his rejection of independent claim 50 under 35 U.S.C. 103(a) based on Sarge et al. in view of Klint.

Rejection of Claim 51 Based on Sarge et al. In View of Klint and Pursley

Claim 51 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sarge et al. in view of Klint and Pursley. The Examiner contends that Sarge et al. and Klint disclose the claimed invention, except for the step of passing the group of filaments through a guide assembly to orient the group of filaments as claimed. The Examiner relies upon Pursley '371 for a teaching of this claimed feature. This rejection is respectfully traversed for the following reasons.

The Examiner states at the bottom of page 7 of the Office Action that "Klint teaches orienting the group of filaments into a plane which is generally perpendicular to the longitudinal axis of the core member (Figure 7)." However, the group of filaments 5 shown in Fig. 7 of Klint are oriented in a plane that is generally coplanar with (i.e., parallel to) the longitudinal axis of the mandrel 7, not perpendicular to the mandrel. For the filaments 5 in Klint to be in a plane which is perpendicular to the longitudinal axis of the mandrel 7, they would need to be illustrated as stacked on top of one another in the vertical direction in the illustrated view of Fig. 7 (instead of side-by-side in the horizontal direction as shown).

Further, as explained above, Pursley '371 does not teach winding a group of filaments simultaneously onto the catheter liner, nor a guide assembly that orients such a group of filaments into a plane which is generally perpendicular to a longitudinal axis of the core member.

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As explained above, the Examiner has failed to identify any teachings in Pursley '371 that correspond to the Applicant's claimed guide assembly recited in claim 51. It is respectfully submitted that there are no such teachings in Pursley '371.


Conclusion

For at least the foregoing reasons, it is respectfully submitted that all of the pending claims in this application are patentable over the applied prior art, and that this application is now in condition for allowance. Early issuance of a Notice of Allowance is respectfully requested.

If the Examiner has any comments or suggestions that could place this application into even better form, the Examiner is encouraged to contact the Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted by:

Dated: October 5, 2005


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